

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addease COMMISSIONER FOR PATENTS PO Box 1430 Alexandra, Virginia 22313-1450 www.webjo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,923	02/21/2006	John M Symington	RM.CH5	8399
7590 07/22/2008 Benita J Rohm			EXAMINER	
Rohm & Mons	anto	PACKARD, BENJAMIN J		
12 Rathbone P. Grosse Pointe,		ART UNIT	PAPER NUMBER	
,			1612	
			MAIL DATE	DELIVERY MODE

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.	Applicant(s)		
10/539,923	SYMINGTON ET AL.		
Examiner	Art Unit		
Benjamin Packard	1612		

Office Action Summary	Examiner	Art Unit	l				
	Benjamin Packard	1612					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPL. WHICHEVER IS LONGER, FROM THE MAILING DV. Extensions of time may be available under the provisions of 3 CPR 11.2 Letterson of time may be available under the provisions of 3 CPR 11.2 Letterson of time may be available under the provisions of 3 CPR 11.2 Letterson of 12 CPR 12.2 Lett	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim- till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	N. nely filed the mailing date of this o D (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on 28 Ag	pril 2008.						
3) Since this application is in condition for allowar	ice except for formal matters, pro	secution as to the	e merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) 1-18 is/are pending in the application.							
4a) Of the above claim(s) 9-18 is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1-8</u> is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or	election requirement.						
Application Papers							
9) The specification is objected to by the Examine	r.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form P	ΓO-152.				
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
1. Certified copies of the priority documents	s have been received.						
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau	(PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)							
1) Notice of References Cited (PTO-892)	4) Interview Summary						
Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da						

Information Disclosure Statement(s) (PTO/S5/08)
 Paper No(s)/Mail Date 2pgs (6/16/2005).

- 5) Notice of Informal Patent Arr lication
 6) Other: _____.

Art Unit: 1612

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claim 1-8; and election of EUDRAGIT RS 30 D brand polymethylmethacrylate (claim 3) which is a type of ammonio methacrylate copolymer, type B USP/NF as set forth in generic claim 2, plasticizer triethyl citrate (claims 4 and 5), in the reply filed on 4/28/2008 is acknowledged.

The requirement is made FINAL.

Claims 9-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 contains the trademark/trade name "EUDRAGIT RS 30 D". Where a trademark or trade name is used in a claim as a limitation to identify or describe a

Art Unit: 1612

particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a specific formulation of polymethylmethacrylate copolymer and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hendrickson et al (US 5,286,497).

Hendrickson et al discloses a method of making a polymeric formulation comprising a mixture of water, Eudragit RS 30 D and plasticizer (column 12 lines 46-58). Among the disclosed plasticizers is triethyl citrate. The amount plasticizer utilized can vary, but will typically be present in the amount of 0 to 40 w/w %, and more preferably about 5-15 w/w % (column 7 lines 16-28).

Art Unit: 1612

In regards to the plasticizer, triethyl citrate, where selection of one named species from a list of alternatives is all that is required to arrive at the instantly claimed subject matter, that species is anticipated. <a href="Expansion-Lambda-Lamba-La

Note, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, the intended use of an inert coating to serve as a temporary mechanical barrier on top of a temporary coating of pharmaceutically active substance applied to the surface of a tooth appears to be met where the prior art teaches the polymeric formation as a coating for an active substance.

The physical properties, such as viscosity, it would have been reasonably expected to be inherent, given that the concentration of components of the disclosed solution appear to be of substantially the same range as those disclosed in the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1612

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendrickson et al (US 5,286,497).

The reference is believed to be anticipatory as discussed above. For the sake of completeness of prosecution, purely arguendo and with regard to this particular ground of rejection only, however, it will be presumed that the prior art differs from the instant claims insofar as it does not suggest the composition as a preferred embodiment. If that is so, it would have been obvious to one skilled in the art to pick and choose among the disclosed plasticizers where the various options are disclosed to provide the same physical property to the solution.

Conclusion

No claims allowed.

Art Unit: 1612

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-3:45 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/ Patent Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612